# Pharmacy NewsCapsule

Division of Supportive Living/Bureau of Quality Assurance July/August 2001

## Alzheimer Treatment Pearls

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A few years ago the alternatives for fighting Alzheimer's disease (AD) were very limited. Over the past few years four new drugs have been approved to specifically treat AD. These new drugs were approved very quickly and studied in a limited number of people. Therefore, it is important to relook at the new medications because much of what we learn about them will be learned after they are approved. In some cases this information will not show up in the Physician's Desk Reference (PDR).

Currently, the four cholinesterase drugs approved for AD are Cognex®, Ariicept®, Exelon®, and Reminyl®. All of these drugs are for mild or moderate AD. Very often people will ask what is mild, moderate and how do you know when to stop the medication? These are legitimate, difficult questions, especially since these medications are extremely expensive and can cause side effects. The answer however is multifaceted and changes as more information is found out about AD.

Current evidence suggests the sooner the diagnosis of AD is made and the faster cholinesterase inhibitors are started the better. Typically these medications will provide patients with stabilization of AD or improvement in their cognition, behavior or functionality.

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## Antipsychotic Tune Up

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The incidence of Alzheimer's and dementia continues to grow as our population ages. Dementia has features of cognitive impairment, behavioral symptoms, mood disturbances, and changes in functional ability. Typically behaviors will fall in the following categories: mood disturbances (depression, anxiety), psychotic symptoms (hallucinations), psychomotor symptoms (aggression, agitation) and vegetative disorders (incontinence).

Accurate diagnosis of the presenting symptoms is a critical first step in the treatment process. Ruling out reversible forms of dementia is paramount and if this has been addressed than non-medication interventions should be considered. Behaviors are the last remaining mode of communication or expression for many individuals with dementia. A person who is bored may pace or scream continuously. A person who does not like loud room noise may become combative.

If medical and environmental causes of behaviors have been ruled out, medications can be considered. The choice of medication should take into consideration the other medications the patient is on, other disease states the patient has, side effects of the medications and the diagnosis, symptom or behavior that is being treated. It makes sense that someone with dementia that is depressed receives an antidepressant medication as a first choice instead of an antipsychotic.

Of course, attention is placed on antipsychotic medications with good reason. These medications are extremely powerful and can easily be used inappropriately so care needs to be taken.

Today we have many new antipsychotics that include Risperdal®, Seroquel®, Geodon®, and Zyprexa®. Each drug has different characteristics, side effects and results. When these agents are used in dementia, monitoring is imperative.

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## New Drugs

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| Brand Name | Generic Name | Use |
|---|---|---|
| **Prozac Weekly** | Fluoxetine | Depression. New formulations that only need to be given once per week. |
| **Prevacid Packets** | Lansoprazole | Gastroesophageal reflux disease. New formulation that is mixed with water for patients who cannot swallow medications. |

## Med Error Corner

Doug Englebert Pharmacy Practice Consultant

Do you think medication errors are overblown? Are the numbers making sense? It probably does not matter. One error that is fatal is enough.

The number of medication errors have been documented in recent published studies and subsequently popularized by the media. Legislators have taken notice. Recently a bill was introduced in the US senate to establish a $1 billion grant program for hospitals and skilled nursing facilities to pay for clinical information systems aimed at cutting medication mistakes. In Wisconsin, proposed state budget include provisions to establish a funding grant to the Wisconsin Patient Safety Institute. Oklahoma has established a law to protect individuals who report medication errors to a national database.

The public is also taking notice and medical and medication errors are being scrutinized. It's time to change some practices to eliminate these errors or additional laws , regulations and lawsuits for healthcare providers will be upcoming. Where can you start?

Recently the National Coordinating Council for Medication Error Reporting & Prevention recommended that verbal and telephone orders should be limited to urgent situations when written or electronic means are not feasible. What are practices related to verbal orders in healthcare facilities? Are these orders used in emergency situations only? Could certain verbal orders be written by a physician and faxed? Could they be emailed?

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## Focus Drug of the Month

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### Reminyl® (galantamine)

Reminyl® is indicated for the treatment of mild to moderate dementia of the Alzheimer's type. Typically Reminyl® will be started at 4 mg twice a day and, if tolerated after four weeks, titrated up to 8mg twice a day. After another 4 weeks the dose may be increased to 12 mg twice a day.

Reminyl should be given twice a day with the morning and evening meals. If Reminyl® is stopped for a period of time it should be restarted at the lowest dose and increased at four week intervals.

The manufacturers labeling indicates that in mild and moderate hepatic and renal function the maximum dose generally should not exceed 16 mg per day. Many elderly individuals will have some level of renal or hepatic deficiency. For those reasons it may be beneficial to err on the cautious side and start low and go slow. Unfortunately the medication comes only in film-coated 4mg, 8 mg and 12 mg tablets. Therefore cutting tablets to titrate doses more slowly than recommended does not appear to be a viable option at this time.

The main reason for dose titration is for side effect purposes. The most common side effects of this medication include nausea, vomiting, weight loss, and dizziness. These side effects appear to be related to dosage increases.

Various liver enzymes metabolize this medication and therefore the potential for drug interactions exists.

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From page 1-Antipsychotic Tune Up

Patients should be monitored for anticholinergic effects (drying out effects like dry mouth, blurry vision and constipation). Patients should be monitored for extrapyramidal symptoms (tardive dyskinesia) and for antihistamine effects (drowsiness).

Besides monitoring for the harmful effects of these medications the goals for the medication should be established and checked. If the medication fails to provide benefit in attaining these goals, stopping the medication would seem appropriate.

New information about Alzheimer's and subsequent treatments is becoming available each day. Newer antipsychotic medications, when used appropriately, are proving helpful in many situations. Appropriate monitoring and continued risk benefit analysis of continuing the medication must be considered in determining continuation of the medication.

Antipsychotics in the right person can drastically improve an individual's quality of life. In others, these medications can drastically harm their quality of life.

From page 1-AD Updates

New evidence suggests that cholinesterase medications can be used for longer periods of time and for severe disease as well. So how long should these medications be used? It varies by patient. Some patients may have unbearable side effects that necessitate stopping the drug. In other cases they may be on the medication for 2-3 years or longer with no problems. Once again the final decision to stop or continue becomes a case-by-case risk benefit evaluation.

Remember, however, that maintaining current status is considered a benefit. Too often these Alzheimer drugs are stopped too soon because it appears cognition has not improved. The trouble with stopping the drug too soon is that individuals could decline rapidly. Restarting the medication typically does not get them all the way back to where they were before the drug was stopped.

One last thing about cholinesterase Alzheimer drugs. There is growing scientific evidence that these medications also have psychotropic effects that can improve behaviors and agitation.

UPDATE: In phase II studies Neotrofin® (leteprinim) is the first drug designed to regenerate neural connections. The studies demonstrated AD patients having statistically significant improvements in memory, attention and judgement. Pivotal phase III studies are due in one year and this exciting drug may be available in two years.

Medications like ketoconazole, erythromycin and paroxetine (Paxil®) can increase the amount of Reminyl® in a person's body. Theoretically this may increase dose-related side effects.

As with all new medications a great deal is still unknown about this medication. All adverse events should be reported to a pharmacist.

## Knock Off Drugs

In a recent *U.S.News* report, an article described the issue of counterfeit drugs facing the United States. The United States has a tightly controlled regulatory system that in the past has virtually made counterfeit drugs nonexistent. However with the rise in Internet drug sales from overseas, border hopping drug purchasers and increasingly sophisticated counterfeiting techniques, there have been recent cases where some counterfeit drugs have made it into US pharmacies and ultimately to patients.

Counterfeit drugs typically may not have any ingredients in them at all or the wrong amount of ingredients. Counterfeiters tend to target high cost medications. Most often examples of counterfeit drugs come from medications purchased abroad. Drug manufacturers and the Food and Drug Administration (FDA) have looked at steps to attack the problem. Some manufacturers are putting "tags" in the medication. This allows them to test the drug with a field tester to identify the real drug. FDA inspectors have been given electronic field databases to visually inspect medications coming in from abroad. Right now consumers would be wise to purchase medications from familiar local pharmacies.

*If there are medications you would like featured here please send an email to Doug at engleda@dhfs.state.wi.us*

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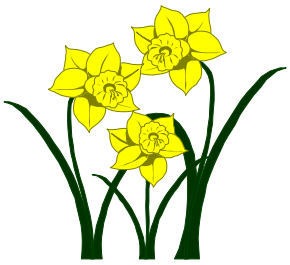
Many of the well known documented errors have very simple solutions. Yet very often these solutions are not used. Sooner or later those facilities that do not implement these well known solutions will find they no longer are practicing quality standards of care. It's time for action!

## Did You Know?

Reminyl®(galantamine) is extracted from the bulbs of Narcissus pseudonarcissus or the Daffodil….a drug from a plant is very common so those who think natural herbal products are safer than drugs…remember many very potent medications come from plants.



## Consultant's Corner

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This section is basically a miscellaneous section that will show up each issue and will contain tidbits of information, most of which will come directly from your questions. If there is a topic you want more detailed information about, please drop me an email at engleda@dhfs.state.wi.us and I'll see what I can find.

1) If a resident is on Buspar®, are behavior monitoring sheets required?

In the State Operations Manual (SOM) for Skilled Nursing Facilities the surveyor guidance provides information related to the federal regulation that addresses unnecessary drugs (42CFR 483.25). In this guidance, when psychotropic medications are used for organic mental syndromes more commonly called dementia, delerium, and amnestic or cognitive disorders, there must be quantitative and objective documentation that supports the medication use. This quantitative and objective documentation is often referred to as "behavior monitoring sheets."

The surveyor guidance also contains lists of numerous psychotropic medications for anxiety, sleep, depression and other psychiatric disorders. Currently Buspar® is not on those lists. Are behavior monitoring sheets required?

The regulation at 42CFR 483.25 defines unnecessary drugs. One condition of an unnecessary drug is inadequate monitoring. If a drug like Buspar® is being used for a behavior, then to determine its effectiveness one needs to monitor that behavior. Just like a patient who is on a blood pressure drug, the blood pressure would be monitored to determine if the drug is effective. The frequency of the monitoring and the way monitoring is documented (behavior monitoring sheets) should be dependent on the medication and the patient receiving the medication. For example, if the behavior prior to the medication was occurring three times a day, then monitoring after the medication should be daily. If the medication works along with other interventions to the point where the behavior now only occurs once or twice per month then behavior monitoring may be by exception where documentation only occurs when the behavior is exhibited.

There is no clear-cut answer. The SOM only provides guidance. Guidance is not the regulation. Therefore, just because a medication is not listed in the guidance does not mean it should not be monitored.

2) I have a patient who is on Coumadin®, Plavix® and aspirin at the same time. Is this ok?

All three of these medications affect blood clotting. Each of them work in different ways and therefore in some cases could be used all at the same time. One must realize individuals who are taking all three medications are at greater risk of adverse drug events like side effects or drug interactions. In this type of patient you would expect close monitoring and patient education so they could recognize potential adverse events.

References are available upon request.